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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,870	12/02/2003	Randall S. Hickle	82021-0033	1625

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EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
04/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hhlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/724,870	HICKLE, RANDALL S.	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2008 and 22 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-31* is/are pending in the application.

4a) Of the above claim(s) *28-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The status of the claims is as follows:

Claims 1, 8, 13, and 15 are previously amended;

Claims 2-7, 9-12, 14- are as originally filed;

Claims 28-31 are withdrawn; and

Claims 16-27 have been cancelled.

Election/Restrictions

2. Claims 28-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 23 January 2008.

Applicant's election with traverse of Group I, claims 1-15, in the reply filed on 23 January 2008 is acknowledged. The traversal is on the ground(s) that

> The Applicant submits that the restriction requirement based on combination and subcombination distinction does not comply with MPEP §806.05(c) because the separate utility of the subcombination suggested by the examiner is not unique to either group. The claimed invention of both groups includes a respiratory monitoring system.
>
> Applicant submits that a combined search and examination of Groups I and II would not pose a serious burden to the Office.

This is not found persuasive because each of Groups I, II, and II are directed to distinct inventions:

Group I, Claims 1-15, drawn to a respiratory monitoring system, classified in class 600, subclass 532;
Group II, Claims 28 and 29, drawn to a respiratory monitoring and gas delivery system, classified in class 128, subclass 204.23; and
Group III, Claims 30 and 31, drawn to a system for delivery sedative and/or
analgesic drugs to a patient, classified in class 600, subclass 300.

The respiratory monitor of Group I is structurally distinct from and not claimed by either the system of Group II or the system of Group III. Applicant has not clearly admitted, or provided evidence, on record that the systems' monitoring devices are obvious variants. Because a search for Group I is only limited to respiratory monitors, i.e. class 600, the broader search for Groups II or III, due to the subject matter directed to delivering gas or delivering sedative and/or analgesic drugs to a patient, would not be required for Group I.

Since these groups are not obvious variants of each other and are different inventive concepts, examination of the groups would require entirely separate searches and consideration of entirely different references with respect to the above subject matter. Thus, the examination of all of the groups would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

3. This application contains claims 28-31 drawn to an invention nonelected with traverse filed on 10 October 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

4. Applicant's arguments, see Remarks, pp. 6-8, filed 22 May 2007, with respect to the rejection of claims 1-7 and 9-15 under 35 U.S.C. 103(a) as being unpatentable over Schnitzer et al, U.S. Patent No. 5,692,497 A ("Schnitzer"), in view of Derrick, U.S. Patent No. 5,046,491 A ("Derrick"), have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

5. Applicant's arguments, see Remarks, pp. 6-8, filed 22 May 2007, with respect to the rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Schnitzer in view of Derrick, have been fully considered, but they are not persuasive.

In response to applicant's argument that "Schnitzer fails to teach or suggest use of a series of LEDs to provide semi-quantitative respiratory information", see Remarks, p. 7, filed 22 May 2007, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Light Emitting Diodes, or LEDs, structurally only emit light and provide visual indications of events depending on the intended use, such as when a parameter exceeds a specified value. They do not structurally provide information, e.g. a quantitative respiratory waveform, although LEDs are capable of indicating the rate of a respiratory parameter by flashing light on and off.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnitzer in view of Derrick, and further in view of Allen et al, U.S. Patent No. 6,142,950 A ("Allen").

Claims 1-15: Schnitzer teaches a respiratory monitoring system 10 comprising: a patient interface (see schematic in fig. 2) comprising a "patient insert" (i.e. endotracheal tube, ETT, or reverse thrust catheter, RTC, see col. 7, ll. 35-37) 12 and a visual display 132, the nasal cannula 12 comprising at least a first nasal capnography port 19 and a first pressure sensor port 64 (see fig. 1B); a respiratory monitor (flow/pressure bi-direct alert, which detects an incorrect flow and/or an undesirable pressure) 18, comprising a pressure sensor; and an electronic controller (central processor or microprocessor 130) 22; wherein the electronic controller manages a drug delivery device, such as a sedation and analgesia system (see col. 2, ll. 29-35, and col. 4, ll. 34-40); user interface allowing a user to enter inputs corresponding to thresholds relating to inhalation or exhalation of the patient (see col. 8, ll. 54-59; wherein pressure waveform analysis and segmentation is used to identify one of respiratory effort and effect (see col. 8, ll. 49-67); wherein alarm conditions are determined based certain criteria including relation to

predetermined thresholds (see col. 9, ll. 25-36); LEDs (see col. 3, ll. 52-59); wherein the visual display 132 is updated in real time (see col. 4, ll. 24-34).

Although Schnitzer does not explicitly teach a nasal cannula, an ear mount and a support band, Schnitzer teaches that the "subsystem 136 is connected for fluid communication with the patient 138, for example, through pneumatic tube (e.g., an ETT) and an RTC (not shown)" (see col. 7, ll. 35-37). However, Derrick teaches an apparatus for gas analysis comprising a nasal cannula 10, an ear mount/support band 28 that is adapted for placement on both ears and provides stability (see figs. 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schnitzer to have a nasal cannula assembly because the scope of Schnitzer's invention encompasses other types of fluid communication with patients other than ETT and RTC, such as nasal cannula.

Neither Schnitzer nor Derrick teaches a visual display that "is adapted to be positioned at a suitable location on the body of a patient such that said indicators are visible to a user while simultaneously observing the patient". However, this display feature is well-known in the art. For example, Allen teaches a respiratory monitoring system (apnea screening device) 10 comprising: a nasal interface/cannula (airflow sensor) 11 with an ear mount (adjustable elastic strap worn around the back of the head and around the ears for good stability and comfort) 20; and a display (display means) 16 (see col. 5, ll. 6-24, and col. 6, ll. 26-38). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Schnitzer in view of Derrick to have a respiratory monitoring system with a visual display adapted to be

positioned at a suitable location on the body of a patient as taught by Allen in order to have a display attached to a patient that is unobtrusive, comfortable, and stable (as stated by Allen, see col. 6, ll. 26-38).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/N. N./
Patent Examiner, Art Unit 3735
04/17/2008